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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,223	10/31/2003	Warren L. Starkebaum	P-11296.00	1509

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MEDTRONIC, INC.
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EXAMINER

TOY, ALEX B

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/698,223	Applicant(s) STARKEBAUM ET AL.	
	Examiner Alex B. Toy	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 31-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-17 and 31-33 is/are allowed.
- 6) ☒ Claim(s) 34-36 and 38-40 is/are rejected.
- 7) ☒ Claim(s) 37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This Office Action is in response to applicant's Request for Continued Examination filed on September 20, 2006. The rejections of claims 1-11, 16, and 17 are withdrawn in view of applicant's amendment. Claims 12-15 are rejoined as they now depend from allowable base claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 34-36 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards (U.S. Pat. No. 6,405,732 B1) in view of Edwards (U.S. Pat. No. 6,254,598 B1).

Art Unit: 3739

Regarding claim 34, Edwards ('732) discloses the step of:

ablating tissue within a stomach with an ablation probe sized to fit the stomach to inhibit the production of acid by the tissue.

Since the device of Edwards ('732) ablates the stomach and fundus (col. 24, ln. 54-56, col. 26, ln. 1-10, and col. 28, ln. 1-4), it must inherently inhibit the production of acid by the stomach tissue.

The claim differs from Edwards ('732) in calling for the steps of:

determining a first acid level of a patient with a hyperacid condition;

determining a second acid level of the patient following a period of time after ablation.

Edwards ('598), however, teaches a pH monitoring catheter (col. 5, ln. 65-67) that inherently determines a first and second acid level as claimed in order to monitor pH levels of a patient with a hyperacid condition. Since the device of Edwards ('732) is also for treating a patient with a hyperacid condition, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a pH monitoring catheter in the device of Edwards ('732) in view of the teaching of Edwards ('598) in order to monitor pH levels of a patient with a hyperacid condition.

In addition, since monitoring pH is disclosed, monitoring inherently implies measuring pH levels over time and comparing these measured levels to determine changes. Therefore, there must inherently be a step of comparing the second acid level with the first acid level to determine whether the second level is lower than the first acid

Art Unit: 3739

level. The examiner maintains that monitoring must inherently include a comparison step; otherwise, monitoring would have no meaning.

Thus, since the device of Edwards ('732) in view of Edwards ('598) performs the steps of claim 34, the Office maintains that the combination inherently discloses the claimed method for reducing stomach acid secretion.

Regarding claim 35, the method of Edwards ('732) in view of Edwards ('598) further comprises ablating tissue within the stomach again if the second acid level is not sufficiently lower than the first acid level. Again, the only ostensible reason for disclosing a pH monitoring catheter in a device for treating a patient with a hyperacid condition would be to adjust treatment based on the feedback from the pH monitoring. Thus, the examiner maintains that the method of Edwards ('732) in view of Edwards ('598) inherently comprises the step of claim 35, since it would be inherent in using pH monitoring feedback to repeat ablation treatment if the measured acid level does not decrease after the first treatment.

Regarding claim 36, Edwards ('732) discloses the method of claim 34 in view of Edwards ('598), wherein the first and second acid levels are first and second esophageal acid levels. Since Edwards ('598) discloses a pH monitor that is used in the esophagus (col. 5, ln. 65-67), it inherently measures esophageal acid levels.

Regarding claim 38, Edwards ('732) discloses the method of claim 34 in view of Edwards ('598), wherein ablating tissue comprises ablating at least a portion of a mucosal lining of the stomach. Since the device of Edwards ('732) ablates the fundus, it must inherently ablate at least a portion of a mucosal lining of the stomach.

Art Unit: 3739

Regarding claim 39, Edwards ('732) discloses the method of claim 34 in view of Edwards ('598), wherein ablating tissue comprises ablating cells that produce stomach acid. Since the device of Edwards ('732) ablates the fundus, it must inherently ablate cells that produce stomach acid.

Regarding claim 40, Edwards ('732) discloses the method of claim 34 in view of Edwards ('598), where the ablation probe comprises at least one of a radio frequency, laser, ultrasonic, microwave, thermal, chemical, mechanical, and cryogenic ablation probe (col. 26, ln. 1-13 and col. 28, ln. 1-4).

Allowable Subject Matter

Claims 1-17 and 31-33 are allowed.

Claim 37 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to claims 1-17, 31-33, and 37 have been fully considered and are persuasive. Therefore, the corresponding rejections have been withdrawn.

Applicant's arguments with respect to claims 34-36 and 38-40 have been fully considered but they are not persuasive.

Art Unit: 3739

Regarding Edwards ('598), applicant argues that the reference does not disclose determining a first and second acid levels. However, as applicant has acknowledged, it is clear from the reference that Edwards ('598) discloses a pH monitoring catheter. As set forth in the above, monitoring inherently implies measuring pH levels over time and comparing these measured levels to determine changes.

Applicant further argues that because Edwards ('598) is only concerned with sensors for monitoring temperature, one of skill in the art would not have been motivated to pick a pH catheter from all of the various possibilities of an elongated medical device. First, that Edwards ('598) discloses sensors for monitoring temperature in no way precludes or negates the earlier disclosure of a pH monitoring catheter. Second, that Edwards ('598) clearly and explicitly discloses the use of a pH monitoring catheter means there is no issue regarding any motivation to "pick" a pH monitoring catheter. One of skill in the art would not need any supposed motivation, since Edwards ('598) already positively recites the inclusion of a pH monitoring catheter.

In response to applicant's argument that there is no suggestion to combine Edwards ('732) in view of Edwards ('598), the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Specifically, applicant argues that because Edwards ('732) discloses his own methods of diagnostic monitoring, there would be no motivation to modify or replace the methods of Edwards ('732) with those of Edwards ('598).

First, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). That Edwards ('732) discloses certain methods of diagnostic monitoring does not mean that it would not have been obvious in view of the prior art of Edwards ('598) to use other methods of monitoring with the device of Edwards ('732), either separately or in combination with the methods already taught by Edwards ('732). This is evident in that Edwards ('732) himself teaches using multiple methods of monitoring and in that Edwards ('598) teaches that temperature sensors can be used in combination with the pH monitoring catheter in a device for treating a hyperacid condition. Therefore, since Edwards ('732) also discloses a device for treating a hyperacid condition with temperature sensors, it would have been obvious, as stated in the preceding rejection, to one of ordinary skill in the art at the time the invention was made to have provided a pH monitoring catheter in the device of Edwards ('732) in view of the teaching of Edwards ('598) in order to monitor pH levels of a patient with a hyperacid condition.

Finally, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon

Art Unit: 3739

hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

Application/Control Number: 10/698,223

Page 9

Art Unit: 3739

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AT *AT*
11/17/06

Michael Peffley
MICHAEL PEFFLEY
PRIMARY EXAMINER